

**Q & A**  
**REGARDING THE RE-SCHEDULING OF**  
**HYDROCODONE-COMBINATION DRUG PRODUCTS**

**Q-1. *Is it true that hydrocodone-combination drug products (HCPs) are being re-scheduled from a Schedule III controlled substance to a Schedule II controlled substance, effective 10/6/14?***

**A** YES. The U.S. Drug Enforcement Administration (DEA) will reclassify HCPs as Schedule II controlled substances on October 6, 2014. Therefore, a pharmacist practicing pharmacy in Texas may not dispense a prescription for a HCP that was issued on or after 10/6/14, unless the prescriber has issued the prescription on a Texas Official C-II Prescription Form [obtained from the Texas Department of Public Safety (DPS)] or through an electronic prescription that is issued in accordance with the DEA and DPS requirements regarding electronic prescriptions for controlled substances.

**Q-2. *If a pharmacist practicing pharmacy in Texas receives a prescription for a hydrocodone-combination product that is dated prior to 10/6/14, may the pharmacist dispense this prescription on or after 10/6/14?***

**A** YES. If a patient presents a new written prescription for a HCP that was issued prior to 10/6/14, the pharmacist may dispense this prescription during the six-month period following the issuance date. For example, on or after 10/6/14, if a pharmacist receives a prescription that was issued on 9/10/14, the pharmacist may dispense that prescription between the date the pharmacy received the prescription and 3/9/15, provided the prescription was a valid prescription [see Q-10 below].

**Q-3. *If a pharmacist practicing pharmacy in Texas receives a prescription for a hydrocodone-combination product that was not issued on a Texas Official C-II Prescription Form but the prescriber failed to write the date on the prescription, may the pharmacist dispense this prescription on or after 10/6/14?***

**A** NO.

**Q-4. *Can REFILLS of prescriptions issued for hydrocodone-combination products prior to 10/6/14 be honored on or after 10/6/14?***

**A** YES. Pharmacists may refill HCP prescriptions that were issued prior to 10/6/14, if refills existed on the original prescription under certain conditions, as explained below:

- If the original prescription (issued prior to 10/6/14) had a specific number of refills authorized on the original prescription, a pharmacist may treat the refills in accordance with federal and state rules for Schedule III controlled substances – i.e., if authorized to be refilled, the prescription shall not be refilled more than 5 times, and shall not be filled or refilled more than six months after the issuance date. Provided, however, under no circumstances may the prescription be filled or refilled on or after 4/8/15 (deadline specified in the DEA Federal Register Notice of re-scheduling of HCPs).
- On or after 10/6/14, if a patient presents a new prescription for a HCP that was issued prior to 10/6/14, and the prescription has a specific number of refills, a pharmacist may dispense the original prescription and can honor the refills on the new prescription with the understanding that the prescription may not be refilled more than 5 times within six months of the date of issuance. For example, if a prescriber issues a prescription on 10/1/14 with three refills, a pharmacist may dispense the original prescription, as well as three refills from on or after 10/6/14 through 3/30/15 (which is six months from the issuance date of 10/1/14), if deemed appropriate following an adequate drug regimen review.
- If the original prescription had NO refills authorized, then a pharmacist may not contact the prescriber for refill authorization on or after 10/6/14.

**Q-5** *If a Texas pharmacist honors a refill on or after 10/6/14, what type of recordkeeping requirements should be followed?*

**A** Refills should be processed as they have been prior to 10/6/14. However, if the pharmacy's software system is not capable of processing refills of HCP prescriptions on or after 10/6/14, then the following procedure may be used:

- If a pharmacist determines the HCP prescription has valid refills remaining, a new prescription record may be created with a unique prescription number each time one of the remaining authorized refills is dispensed (i.e., a new prescription number must be assigned); each new prescription record must be cross-referenced with the original HCP prescription and bear all information required for a new prescription, including the following information:
  - original HCP prescription number;
  - original issue date of HCP prescription;
  - original number of refills; and
  - which refill is represented by the current fill (e.g., refill 2 of 5);
- Each new prescription record that is created (as described above) must be filed in the pharmacy's C-II file;
- Pharmacy personnel (pharmacists and designated technicians) must also document on the original hard-copy HCP prescription (or in the pharmacy's computer system), each time one of the remaining authorized refills is dispensed; and
- Any documentation that is maintained in the pharmacy's computer system must be maintained as a "permanent" record. If documentation made in the "notes" section is not considered as a permanent record, the documentation should be made in the data entry field for the prescriber's directions for use (i.e., the "sig" field). This information would be printed on the prescription label that would subsequently be affixed to the prescription vial dispensed to the patient. For example: SIG: "Take ... as needed for pain. Original Rx #111111. Issue date 10/1/4. Refill 2 of 5."

The pharmacy must maintain the documentation described above to support the validity that the dispensing of an HCP after 10/6/14 was pursuant to an existing authorized refill rather than pursuant to an Official C-II Prescription Form. The procedures for submitting an authorized refill of an HCP prescription to the Texas Prescription Drug Monitoring Program is described in Q-6 below.

**Q-6** *Will the Prescription Access Texas (PAT) Program accept the prescription for a hydrocodone-combination product without a control number?*

**A** NO. HOWEVER, the Texas Department of Public Safety (DPS), who administers the Texas Prescription Program, has developed a system to accommodate pharmacies who wish to dispense a HCP pursuant to an existing authorized refill [as described in Q-5 above] and have the capability to assign a placeholder DPS Control Number for HCP prescriptions issued prior to 10/6/14. Specifically, DPS has created a placeholder value for the DPS Control Number that pharmacists may use for all reclassified HCP prescriptions. The placeholder DPS Control Number is 080000000000 – i.e., 08 followed by 10 zeroes. DPS has advised TSBP of the following:

- When a prescription is received containing the specified placeholder control number, DPS will accept the prescription as long as it is dispensed between 10/6/14 and 4/7/15.
- This placeholder control number will only be valid during the "grace period" of 10/6/14 to 4/7/15. In other words, this number will be invalid on and after 4/8/15.
- Any HCP prescription that is dispensed after 4/7/15 with the Control Number of 080000000000 will be rejected by DPS and DPS will not evaluate the NDC number to determine if the prescription was issued for an HCP.

- Q-7** *On or after 10/6/14, can a Texas pharmacist refuse to honor the remaining authorized refills on a prescription for a hydrocodone-combination product that was previously dispensed by the pharmacy prior to 10/6/14?*
- A** Pharmacists should use good professional judgment and act in the best interest of their patients. If the pharmacist does not want to honor authorized refill(s) of a valid prescription, the pharmacist should offer to transfer the prescription to another pharmacy who will accept the transfer of the refill(s). Transfers of authorized refills are allowed from 10/6/14 through 4/7/15 (the six-month period set forth by DEA). To assist patients, pharmacists who are not going to honor remaining authorized refills of a valid prescription may wish to contact a near-by pharmacy to determine if that pharmacy would accept a transfer of a HCP prescription. NOTE: If a patient wants his/her prescription transferred to another pharmacy, TSBP rules require the pharmacy to transfer the prescription.
- Q-8** *Must a DEA Form 222 be executed in order to purchase hydrocodone-combination products on or after 10/6/14?*
- A** YES. Beginning 10/6/14, HCPs will be ordered in the same manner that you purchase other Schedule II controlled substances.
- Q-9.** *Must an inventory of all hydrocodone-combination products be taken on 10/6/14?*
- A** YES. An exact count of all HCPs must be taken on 10/6/14, given that HCPs will become a Schedule II controlled substance on that day. Your inventory should be taken at the close of business on 10/5/14 or at the opening of business on 10/6/14. NOTE: TSBP recommends that this inventory be notarized, but notarization is not required.
- Q-10.** *If a pharmacist receives a Texas Official C-II Prescription Form for a hydrocodone-combination product, is the pharmacist required to dispense the prescription?*
- A** NO. You must continue to use your professional judgment when filling any prescription for a controlled substance. The mere fact that the HCP is issued on a Texas Official C-II Prescription Form does not mean that the prescription is a valid prescription. Pharmacists have a corresponding responsibility to ensure that a prescription is issued pursuant to a legitimate medical purpose in the usual course of professional practice and that a valid doctor-patient relationship exists.
- Q-11.** *Are hydrocodone-combination products required to be stored in a safe or locked cabinet?*
- A** All pharmacies must maintain proper security for HCPs and all controlled substances. A Class C (Institutional) Pharmacy must have locked storage for all Schedule II controlled substances. However, a Class A (Community) Pharmacy may place HCPs in a locked storage area or may place HCPs on the pharmacy's shelves with the other dispensing stock.
- Q-12.** *How should Texas pharmacists handle prescriptions that are issued by mid-level practitioners [i.e., a physician assistant (PA) and advanced practice registered nurse (APRN)]?*
- A** The answer depends upon when the prescription was issued, as explained below:
- If the HCP prescription is issued prior to 10/6/14, the PA or APRN holds valid DEA and DPS registrations to prescribe Schedule III-N controlled substances, and the dispensing pharmacist determines the prescription is valid [see Q-10 above], then:
    - a pharmacist may dispense the original prescription and all authorized refills under the circumstances explained in Q-2 and Q-4 above; and
    - a pharmacist may honor the authorized refills that existed on the original prescription that the pharmacy previously dispensed, under the circumstances explained in Q-4, Q-5, and Q-6 above.
  - If the HCP prescription is issued on or after 10/6/14, the PA or APRN must be registered to prescribe a Schedule II-N controlled substance, and the dispensing pharmacist determines the prescription is valid, the pharmacist may dispense the prescription if the prescriber issued the prescription on a Texas Official C-II Prescription Form or through an electronic prescription that was issued in accordance with the DEA and DPS requirements regarding electronic prescriptions for controlled substances.